

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference A161822	FOR FURTHER ACTION		See item 4 below
International application No. PCT/IB2004/003652	International filing date (<i>day/month/year</i>) 05 November 2004 (05.11.2004)	Priority date (<i>day/month/year</i>) 13 November 2003 (13.11.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant QUIMICA SINTETICA, S.A.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 15 May 2006 (15.05.2006) Authorized officer <div style="text-align: center; font-weight: bold;">Cecile Chatel</div> Telephone No. +41 22 338 70 60
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 25 FEB 2005

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/B2004/003652

International filing date (day/month/year)
05.11.2004

Priority date (day/month/year)
13.11.2003

International Patent Classification (IPC) or both national classification and IPC
C07D215/56, A61K31/496

Applicant
QUIMICA SINTETICA, S.A.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Fanni, S

Telephone No. +49 89 2399-8712



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/003652

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/003652

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, Inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1
Inventive step (IS)	Yes: Claims	
	No: Claims	1
Industrial applicability (IA)	Yes: Claims	1
	No: Claims	

2. Citations and explanations

see separate sheet

ITEM V

Reference is made to the following documents:

- D1: EP-A-0 230 295 (KYORIN PHARMACEUTICAL CO., LTD) 29 July 1987 (1987-07-29)
- D2: EP-A-0 805 156 (KYORIN PHARMACEUTICAL CO., LTD) 5 November 1997 (1997-11-05)
- D3: WO 02/22126 A (BRISTOL-MYERS SQUIBB COMPANY) 21 March 2002 (2002-03-21)

NOVELTY (Article 33(2) PCT)

In general, to allow claims for products defined in terms of process the product as such should be new and inventive. The fact that a compound is produced by means of a new process does not render the compound novel. It should be noted that product-by-process claims are allowable only in cases where the product cannot be defined in any other way. This is not the case for the current product claim 1, since the claimed crystalline form of formula I is defined in the description in terms of physical parameters (e.g. XRD pattern and water content).

Thus, although the XRD peak values given on pages 4 and 5 of the present description might establish novelty over D1, and the present water content (% in weight) might establish novelty over D2 and D3 (cf D2, Example 1; D3, Example 2), the crystalline form as defined in present claim 1 cannot be unambiguously and exclusively attributed to the crystalline form described in the present description, i.e. unambiguously distinguished from the crystalline forms described in the prior art documents D1-D3. Novelty for the present set of claims cannot therefore be acknowledged.

INVENTIVE STEP (Article 33(3) PCT)

The present subject-matter is directed towards the provision of a further crystalline form of gatifloxacin.

Crystalline form of gatifloxacin are known from the prior art (cf D1-D3).

The crystalline form as described in the present description appears to differ from those disclosed in D1-D3 on account of a different XRD pattern (D1) or different water content (D2-D3). D1 appears to have a water content closest to the present crystalline form and is therefore considered to be the closest prior art.

The problem to be solved by the present subject matter vis-à-vis D1 is considered to be the provision of a further crystalline form of gatifloxacin having unexpected properties when compared with the closest prior art compound. The stability (cf table 1) of the present form might establish an inventive step over D1. However, such inventive step can be established only in a comparative manner, i.e. proving that the claimed stability is an intrinsic property distinguishing the present form from the closest prior art form from D1 (e.g. comparing stability data from both the present compounds and the closest prior art compounds from D1). Thus, since the present description only provides data for the present compound, an inventive step cannot be acknowledged for the present subject matter.